REMARKS

With this amendment, claims 1-20 are pending in the application. Claims 1, 12 and 15 are the only claims in independent form.

Remarks Directed Towards Claim Rejections

Remarks Directed to Rejection under 35 U.S.C. 112, Second Paragraph

Claims 1-14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Firstly, the expression "capable of substantially solubilizing" in claims 1 and 12 is cited as rendering the claims indefinite because the specification is not believed to provide a standard for "ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." (Paper 6, page 2, para. 3)

The specification in the instant case provides adequate guidance to apprise one of skill in the art of the scope of the invention. In particular, the teaching of the present invention represented by the phrases "... wherein said solubilizing agent is capable of substantially solubilizing said drug particle" (claim 1) and "... having volume sufficient to substantially solubilize said particle" (claim 12) is supported by the specification. For example, the specification states that the "... size of the diffusional boundary layer is maintained at a volume sufficient to solubilize substantially the entire drug particle." (p.4, lines 14-15) Further, the specification details the relationship between the mass of a drug particle, the volume of the boundary layer and the solubility of the drug in Equation 2 (p.5, line 12). The specification also includes aqueous solubility data for selected drugs in Table 1 on page 18. Taken together, the relevant sections of the specification describe the ratio of the mass of the drug particle to the volume of the diffusional boundary layer solubilizing the drug particle to

an extent greater than 0.001 milligram per milliliter. Thus, claims 1 and 12 have been amended to clarify the scope of the claims by including specific teachings of the invention implied by the phrase "substantially solubilize." In view of these remarks and the amendments, it is respectfully requested that the rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, be withdrawn.

The claims are further rejected as indefinite under 35 U.S.C. 112, second paragraph, because "it is unclear whether the solubilizing agent is part of the boundary layer or enclosed by the boundary layer." (Paper 6, page 2, para. 4) Claim 1 describes the matrix and the solubilizing agent as forming the diffusional boundary layer. Claim 11 has been amended to make it clear that the solubilizing agent is part of the boundary layer and that, in one embodiment, the matrix component of the boundary layer substantially encloses the solubilizing agent component of the boundary layer. Thus, by these remarks and the amendments Applicant has clarified that the solubilizing agent is part of the boundary layer of the present invention and respectfully requests that the rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, be withdrawn.

Claim 11 is further rejected as indefinite because it includes the term "substantially encloses" in defining the relationship between the boundary layer, drug particle and solubilizing agent. (Paper 6, page 2, para. 5) Claim 11 has been amended to clarify that the matrix encloses the drug particle and the solubilizing agent in one embodiment. In view of these remarks and the amendments, it is respectfully requested that the rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. 102(b)

Claims 1, 2, 5, 6 and 8-14 were held to lack novelty under 35 U.S.C. 102(b) as being anticipated by Amidon et al. (U.S. Patent 5,834,022).

In order for the cited reference to have anticipated Applicant's invention, the reference must teach every element of the claim. (MPEP, 7th Ed., revision 1, 2131) Independent claims 1 and 12 of the present invention teach that the ratio of the mass of the drug particle to the volume of the diffusional boundary layer solubilizing the drug particle to an extent greater than 0.001 milligram per milliliter.

Amidon et al. is cited as teaching a coating composition consisting essentially of gelatin and lecithin, having a drug disposed within the boundary layer. However, in contrast to the present claims, Amidon et al. does not teach the relationship between the mass of the drug particle and the volume of the diffusional boundary layer in solubilizing the drug particle taught in the present invention. On the basis of these arguments and the amendments, it is submitted that claims 1, 2, 5, 6 and 8-14 are not anticipated under 35 U.S.C. 102(b) by Amidon et al. Therefore, it is respectfully requested that the rejection of claims 1, 2, 5, 6 and 8-14 as anticipated by Amidon et al. be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. 103(a)

Claims 3, 4 and 7 were held to be unpatentable under 35 U.S.C. 103(a) for being obvious over Amidon et al. (U.S. Patent 5,834,022) in view of Woo (U.S. Patent 5,589,455) and Gennaro et al. (Remington's Pharmaceutical Sciences, 18th ed., 1990, page 1662-1664). In view of the Applicant's belief as to the allowability of the independent claims, dependent claims 3, 4 and 7 are likewise submitted to be allowable. It is respectfully requested that the rejection under 35 U.S.C. 103(a) be withdrawn.

Summary

Claims 1-20 are the pending claims in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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DATE OF DEPOSIT April 2, 2002

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Janice R. Kucken

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS:

Claim 1 has been amended as follows:

1. (Amended) A pharmaceutical delivery vehicle, said delivery vehicle comprising:

a drug particle having an initial mass disposed within a diffusional boundary layer comprising a matrix and a solubilizing agent, the diffusional boundary layer having a volume;

said matrix and said solubilizing agent forming the diffusional boundary layer,

the ratio of the initial mass of the drug particle to the volume of the diffusional boundary layer being such that the drug particle is solubilized to an extent greater than 0.001 milligram per milliliter [wherein said solubilizing agent is capable of substantially solubilizing said drug particle].

Claim 11 has been amended as follows:

11. (Amended) A delivery vehicle according to claim 1, wherein said [boundary layer] matrix [substantially] encloses said drug particle and said solubilizing agent.

Claim 12 has been amended as follows:

12. A pharmaceutical delivery vehicle, said delivery vehicle comprising:

a drug particle having an initial mass disposed within a diffusional boundary layer having a volume, [sufficient to substantially solubilize said drug particle] the ratio of the initial mass of the drug particle to the volume of the diffusional boundary

layer being such that the drug particle is solubilized to an extent greater than 0.001 milligram per milliliter.

New claims 15-20 have been added.